

**Amendments to the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1-28 (Canceled).

29 (Currently Amended). A pH-independent extended release dosage form, comprising:

venlafaxine hydrochloride in an amount of 30-60% based on the total weight of the dosage form;

said venlafaxine hydrochloride being coated on a nonpareil inert core, said nonpareil inert core comprising 30-60% based on the total weight of the dosage form;

the venlafaxine hydrochloride being optionally connected to a binder in a binder amount of 0.5-10% based on the total weight of the dosage form;

an isolating layer coating said venlafaxine hydrochloride and comprising 0.5-10% based on the total weight of the dosage form, said isolating layer being selected from the group consisting of polyvinylpyrrolidone, hydroxypropylcellulose, hydroxypropylmethylcellulose, carrageenan and GMS; and

a controlled release layer coated over said ~~hydrophilic polymeric or CMS~~isolating layer, said controlled release layer comprising a ~~hydrophobic controlled release~~ polymer optionally mixed with a plasticizer, said ~~hydrophobic controlled release~~ polymer comprising 2-15% based on the total weight of the dosage form, said controlled release polymer being selected from the group consisting of ammonio methacrylate copolymer, hydroxypropylmethylcellulose, ethyl cellulose, and cellulose acetate, and said optional plasticizer, when present, comprising 0.1-2% based on the total weight of the dosage form;  
~~\_\_\_\_\_ said controlled release layer permitting controlled release of the venlafaxine hydrochloride over an approximately 24 hour period;~~

wherein said layers cause the venlafaxine hydrochloride to be released in a pH-independent manner over an approximately 24 hour period after oral administration.

30 (Currently Amended). The unit dosage form of claim 29, wherein at least one of said controlled release layer, said ~~hydrophilic polymeric or CMS~~isolating layer, and said optional binder, when present, comprises hydroxypropylmethylcellulose.

31 (Currently Amended). A pH-independent extended release composition, comprising:

a nonpareil inert core;

a venlafaxine hydrochloride layer coating said inert core, said venlafaxine hydrochloride comprising 30-60% based on the total weight of the composition; and

a ~~hydrophobic-controlled release~~ polymer layer coating said venlafaxine hydrochloride layer, said controlled release polymer being selected from the group consisting of ammonio methacrylate copolymer, hydroxypropylmethylcellulose, ethyl cellulose, and cellulose acetate,

said ~~hydrophobic-controlled release~~ polymer layer comprising 2-15% based on the total weight of the composition,

~~said hydrophobic polymer layer enabling controlled release of the venlafaxine hydrochloride over an extended time period,~~

wherein said layers permit pH-independent release of the venlafaxine hydrochloride over an extended time period after oral administration.

32 (Currently Amended). The composition according to claim 31, further comprising ~~glycerol monostearate (GMS) or a hydrophilic polymer~~ an isolating layer coating said venlafaxine hydrochloride layer, said ~~GMS or hydrophilic polymer~~ isolating layer being selected from the group consisting of polyvinylpyrrolidone, hydroxypropylcellulose, hydroxypropylmethylcellulose, carrageenan and GMS, and providing

at least one function of isolating, protecting and separating the venlafaxine hydrochloride layer from the hydrophobic polymer layer.

33 (Currently Amended). The composition according to claim 32, wherein the ~~CMS or hydrophilic polymer~~ isolating layer comprises a polymer selected from the group consisting of polyvinylpyrrolidone, hydroxypropylcellulose, hydroxypropylmethylcellulose, ~~microcrystalline cellulose,~~ and carrageenan.

34 (Currently Amended). The composition according to claim 32, wherein the ~~CMS or hydrophilic polymer~~ isolating layer is 0.5-10% based on the total weight of the composition.

35 (Previously Presented). The composition according to claim 31, wherein the venlafaxine hydrochloride layer further comprises a binder.

36 (Previously Presented). The composition according to claim 35, wherein the binder is selected from the group consisting of polyvinylpyrrolidone, hydroxypropylcellulose and hydroxypropylmethylcellulose.

37 (Previously Presented). The composition according to claim 35, wherein the binder is 0.5-10% based on the total weight of the composition.

38 (Currently Amended). The composition according to claim 31, wherein the ~~hydrophobic-controlled release~~ layer further comprises a plasticizer.

39 (Previously Presented). The composition according to claim 38, wherein the plasticizer is 0.1-2% based on the total weight of the composition.

40 (Previously Presented). The composition according to claim 38, wherein the plasticizer is selected from the group consisting of castor oil, dibutyl sebacate, glyceryl monostearate, diethyl phthalate, glyceryl triheptanoate, hydroxypropyl cellulose, polyethylene glycol, and triethyl citrate.

41 (Cancelled).

42 (Previously Presented). The composition according to claim 31, wherein the nonpareil inert core is an inert sugar core or a microcrystalline cellulose core.

43 (Previously Presented). The composition according to claim 42, wherein the core is 30-60% based on the total weight of said composition.

44 (Withdrawn). In a method for administering venlafaxine hydrochloride to a patient in need thereof, comprising administering the venlafaxine hydrochloride as an extended release composition to the patient, the improvement

wherein the extended release composition is in accordance with claim 31.

45 (Withdrawn/Currently Amended). A method for preparing an extended release composition in accordance with claim 31, comprising:

providing the nonpareil inert core;

coating the nonpareil inert core with a layer of the venlafaxine hydrochloride; and

coating the venlafaxine hydrochloride layer with the ~~hydrophobic-controlled release polymer~~ layer.

46 (Currently Amended). The composition of claim 29, wherein the ~~hydrophilic polymeric or CMS~~ isolating layer comprises polyvinylpyrrolidone, the ~~hydrophobic-controlled release polymer~~ is ethyl cellulose and the controlled release layer further comprises a dibutyl sebacate plasticizer.

47 (Currently Amended). A pH-independent extended release dosage form having specified dissolution characteristics ~~that are equivalent to those of the venlafaxine hydrochloride dosage form sold under the proprietary name EFFEXOR XR,~~ comprising:

venlafaxine hydrochloride in an amount of 30-60% based on the total weight of the dosage form;

said venlafaxine hydrochloride being coated on a nonpareil inert core, said nonpareil inert core comprising 30-60% based on the total weight of the dosage form;

the venlafaxine hydrochloride being optionally connected to a binder in a binder amount of 0.5-10% based on the total weight of the dosage form wherein said binder, when present, is selected from the group consisting of polyvinylpyrrolidone, hydroxypropylcellulose and hydroxypropylmethylcellulose;

an isolating a ~~hydrophilic polymeric or glycerol monostearate (GMS)~~ layer coating said venlafaxine hydrochloride and comprising 0.5-10% based on the total weight of the dosage form, said isolating layer being selected from the group consisting of polyvinylpyrrolidone, hydroxypropylcellulose, hydroxypropylmethylcellulose, carrageenan and GMS; and

a controlled release layer coated over said ~~hydrophilic polymeric or GMS~~ isolating layer, said controlled release layer comprising a ~~hydrophobic-controlled release~~ polymer mixed with a plasticizer, said ~~hydrophobic-controlled release~~ polymer comprising 2-15% based on the total weight of the dosage form, said controlled release polymer being selected from the group consisting of ammonio methacrylate copolymer, hydroxypropylmethylcellulose, ethyl cellulose, and cellulose

acetate, and said plasticizer comprising 0.1-2% based on the total weight of the dosage form;

the parameters being selected so as to control release of the venlafaxine hydrochloride over an approximately 24 hour period in a manner that ~~is equivalent to the dissolution characteristics of EFFEXOR XR~~ the following pH and rpm independent in vitro dissolution specifications are obtained:

| <u>Time (hrs)</u> | <u>Average % venlafaxine HCl release</u> |
|-------------------|--|
| <u>2</u>          | <u>&lt;30</u>                            |
| <u>4</u>          | <u>30-55</u>                             |
| <u>8</u>          | <u>55-80</u>                             |
| <u>12</u>         | <u>65-90</u>                             |
| <u>24</u>         | <u>&gt;80</u>                            |

48 (Currently Amended). The composition of claim 47, wherein the ~~hydrophilic polymeric or CMS~~ isolating layer comprises polyvinylpyrrolidone, the ~~hydrophobic-controlled release~~ polymer is ethyl cellulose and the controlled release layer further comprises a dibutyl sebacate plasticizer.

49 (New). The unit dosage form of claim 29, wherein said binder is selected from the group consisting of



In re of Yoram SELA  
Application No. 10/500,634  
Response to Office Action of October 27, 2010

polyvinylpyrrolidone, hydroxypropylcellulose, and  
hydroxypropylmethylcellulose.